

### **REMARKS**

At the outset, Applicant wishes to thank Examiners Jean-Louis and Padmanabhan for taking the time to meet with Applicant's representative and discuss the outstanding grounds of rejection as well as Applicant's proposed response. Applicant submits that the instant remarks not only address the grounds of rejection set forth in the outstanding Non-Final Rejection of April 1, 2008 but also the concerns and suggestions raised by the Examiners in the course of the interview of June 11, 2008, the substance of which is set forth in the Interview Summary mailed July 16, 2008. In particular, in an effort to expedite prosecution, Applicant has limited elected claim 9 to the "treatment" of a skin condition. Applicant has further limited the claim to the administration of a semi-solid composition formulated for topical administration comprising a "purified" polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. Support for this amendment is found in the as-filed specification and claims, particularly p. 14, lines 27-28 ("The liberated fatty acids were further purified by subjecting them to the urea inclusion process several times.") and Figure 1. Thus, Applicant submits that no new matter has been added. However, Applicant reiterates that this amendment is presented solely for the purpose of expediting prosecution and should not be construed as Applicant's agreement with or acquiescence to the grounds of rejection previously set forth.

Pursuant to the entry of the instant amendment, claims 1-29 are presently pending. Applicant respectfully submits that, of these, claims 9-11, 15, 18-21, and 26-29 read on the elected invention of Group II, directed to a method of treating a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation with a semi-solid composition formulated for topical administration comprising a purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutical carrier.

Applicant respectfully submits that the instant response renders moot the outstanding claim rejections and places the instant application in condition for allowance. Further to this position, Applicant submits the following remarks:

### **Restriction/Election**

At present there is some confusion on the record as to whether claim 11 is under consideration or withdrawn. Applicant may have initiated the confusion by inadvertently designating claim 11 as "withdrawn" in the previous response. However, it seems that the

substance of claim 11 was indeed addressed in the previous office action. See, for example, the Office Action Summary page, wherein claims 1-8, 12-14, 16, 17, and 22-25 are indicated as withdrawn from consideration and claims 9-11, 15, 18-21, and 26-29 are indicated as rejected. In any event, the designation error is corrected in the instant response. Accordingly, claims 9-11, 15, 18-21, and 26-29 are presently under consideration.

*Rejections under 35 U.S.C. § 112, First Paragraph*

The Examiner maintained the rejection of claims 9-11 and 26-29 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. According to the Examiner, while the specification is enabling for the treatment of certain skin conditions, such as fungal and/or bacterial infections, it does not reasonably provide enablement for the prevention of all skin conditions. According to the Examiner, the term “prevention” is an absolute term which implies complete cessation. Given that “no known disease can be absolutely prevented at this time” and the fact that “the prevention of all skin conditions would entail different mechanisms of action”, the Examiner concludes that the scope of the instantly claimed invention exceeds the scope of enablement.

While Applicant respectfully disagrees with the Examiner’s characterization of the term “prevent”, he has nevertheless canceled the term “preventing” from elected claim 9, thereby rendering moot the instant rejection. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 9-11 and 26-29 under 35 U.S.C. § 112, first paragraph in view of the amendments and remarks herein.

*Double Patenting Rejections*

Claims 9, 11, 15, and 26-29 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 11, and 23-24 of copending Application No. 10/809,856. In that the ‘856 application has been abandoned, Applicant respectfully submits that this rejection is now moot. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Claims 9, 11, and 15 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 and 11 of copending Application No. 12/043,052. While Applicant respectfully disagrees with the Examiner’s

characterization of the respective claim sets, Applicant nevertheless will consider submission of a terminal disclaimer upon indication of allowable subject matter.

Rejections under 35 U.S.C. § 103

Ahmad in view of Berg:

Claims 9-11, 15, 18-21, and 26 remain rejected under 35 U.S.C. § 103(a) as being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988). Applicant's rebuttal comments notwithstanding, the Examiner maintains that "it would have been obvious to one of ordinary skill in the art to use *Nigella sativa*, a member of the Ranunculaceae [family], for the treatment of diaper rash since Ahmad teaches that members of Ranunculaceae can be used for the treatment of skin diseases and given that Berg teaches that diaper rash is a skin disease."

Applicant continues to dispute the Examiner's interpretation of the prior art teachings as well as her conclusion of obviousness. To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicant respectfully submits that the instant rejection fails on all three counts.

With regard to motivation, the burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Merely suggesting that a reference could be physically modified does not render the resulting modification "obvious" unless the prior art also suggests the desirability of the modification. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Likewise, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" is not sufficient to establish

a *prima facie* case of obviousness without some objective reason to modify or combine the teachings of the reference(s). *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000)

In this case, the Examiner states that “[g]iven that Ahmad teaches that member of the family Ranunculaceae are useful for treating skin diseases”, “that *Nigella sativa* is a member of the aforementioned family”, and that “Berg discloses that diaper rash is a type of skin disease”, one of ordinary skill in the art would have been motivated to utilize the composition of Ahmad to treat diaper rash (see p. 17 of the Office Action of April 1, 2008). However, at the time of the invention of Ahmad et al., people had been experimenting for decades with Ranunculaceae plants and to date had discovered a variety of therapeutic uses thereof, such uses ranging from the treatment of “fevers, boils, and rheumatism” (Ahmad, [0018]) to the treatment of conditions such as “skin diseases, hemorrhoids, cancer, endothelial cell progression, decrease in the production of the angiogenic protein-fibroblastic growth factor made by tumor cells and inhibition of the growth factor made for endothelial cells” (Ahmad, [0019]). As discussed in the personal interview of June 11<sup>th</sup>, the Ranunculaceae family consists of 51 to 88 genera, totaling about 2500 species (See Appendix A: Wikipedia citation for “Ranunculeae”). While Ahmad et al. highlight the use of *Nigella sativa*, preferably in combination with one or more extracts from the genera *Actaea*, *Anemone*, and *Ranunculus*, they do so solely in the context of immunomodulation and the treatment of liver diseases, particularly those with viral etiology (e.g., hepatitis). Nowhere in the Ahmad reference is there a suggestion that, of all the species of Ranunculeae, of all the potential pharmaceutical uses thereof, it is desirable to utilize the extracts of *Nigella sativa* in the treatment of skin diseases. In fact, Applicant submits that the likelihood of arriving at a method comprised of these select variables “would be the same as discovering the combination of a safe by the inspection of its dials”. *Ex parte Garvey*, 41 USPQ 583 (POBA 1939); *Ex parte Starr*, 44, USPQ 545 (POBA 1938).

It is well settled that a generic disclosure does not always disclose or suggest every species encompassed therein. *Ex parte A*, 17 USPQ2d 1716 (BPAI, 1990). When a particular compound, composition or combination is not specifically named, but instead it is necessary to, in hindsight, select portions of teachings within a reference and combine them, suggestion can only be found if the class or classes of substituents are sufficiently limited or well delineated. In other words, only when one of ordinary skill in the art can “at once envisage” the specific

combination within the generic disclosure can the specific combination be deemed anticipated. Similarly, when one is required to pick and choose among a myriad of possibilities (e.g., select one botanical species from among thousands, one disease from a myriad of options, etc.) to arrive at one particular combination, obviousness can only be found if objective evidence leads one in the proposed direction. *Orthopedic Equipment Company v. United States*, 702 F.2d 1005 (Fed. Cir. 1983). To that end, the courts suggest one should look to the disclosed preferred embodiments to determine which combinations are fairly taught. See *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In this case, the Ahmad reference mentions the word “skin” exactly twice – once in paragraph [0019] (discussed above) and a second time in paragraph [0005], wherein “skin” reactions are mentioned as possible negative side effects of interferon therapy. While the Ahmad compositions are generically described as suitable for “oral, parenteral, topical, and nasal delivery as well as by suppository, contemplating solid dosage-forms, liquids, suspensions, intramuscular, subcutaneous, intravenous, and transdermal delivery systems”, the examples and preferred embodiments all relate to the treatment of hepatitis C with an intramuscular injection preparation. Accordingly, given that neither skin diseases nor topical administration is separately identified by Ahmad et al. as preferred or illustrated in any of the recited examples, much less identified as useful together, Applicant respectfully submits that one could arrive at the presently claimed combination only through a meticulous selection of substituents for which Ahmad provides no motivation or guidance, something akin to finding a needle in a haystack.

Thus, while Ahmad arguably suggests that “members” of Ranunculaceae “can be used” for the treatment of “skin diseases”, there is no clear teaching of the use of *Nigella sativa* (one of the 2500 possible Ranunculaceae family botanicals), much less one specific formulation thereof (i.e., a semi-solid composition formulated for topical administration comprising {claim 9} or consisting essentially of {claim 15} a purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds) in connection with the treatment of skin disorders, much less a specific type of skin disorder (e.g., skin conditions arising from fungal infection, bacterial infection, allergic reaction or inflammation). Accordingly, Applicant submits that not only would one of skill in the art not have been motivated by the generic teachings of Ahmad to select *Nigella sativa* for further consideration in the context of the topical treatment of skin disease but he would further not have been motivated to combine the Ahmad teachings with those of Berg to

arrive at the invention of the pending claims. For this reason, Applicant submits that the Examiner's conclusion of obviousness is improper and should be withdrawn.

As for the requirement of a reasonable expectation of success, while obviousness does not require absolute predictability, at least some degree of predictability is required. Even the expanded obviousness doctrine promulgated by *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) acknowledges that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. Accordingly, evidence showing there was no reasonable expectation of success supports a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

As discussed above, neither prior art reference suggests the suitability of *Nigella sativa* in the treatment of skin conditions arising from fungal infection, bacterial infection, allergic reaction, or inflammation, more particularly skin conditions such as diaper rash. Moreover, in that the genus of "skin diseases" is widely variable, encompassing hundreds of divergent conditions ranging from acne to warts (See Appendix B: Wikipedia citation for "Skin Disease"), Applicant submits that one could not reasonably predict the efficacy of *Nigella sativa* in the treatment of skin disorders merely from the disclosure that some species of Ranunculaceae botanical are known for the treatment of "skin diseases". In fact, the Examiner has gone on record as characterizing skin conditions as "unduly unpredictable" (noting that various known skin conditions are characterized by "different etiologies" and "different mechanisms of action"). Accordingly, given the admitted lack of predictability in the art, there is simply no reason to believe that the purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* and formulated for topical administration with a suitable pharmaceutical carrier would be efficacious in the treatment of those select skin conditions arising from fungal infection, bacterial infection, allergic reaction or inflammation. For this additional reason, Applicant submits that the Examiner's conclusion of obviousness is improper and should be withdrawn.

Finally, obviousness requires that the prior art reference (or references when combined) teach or suggest all the claim limitations. As the Examiner correctly notes, Ahmad discloses the use of crude extracts, i.e., ground plant material extracted in a polar solvent and subsequently vacuum concentrated (Ahmad, [0065]). As such, the Ahmad extract is comprised of numerous components, including fatty acids, glyceryl esters, volatile oils, and total sterols (see Applicant's

Figure 1), components expressly excluded from pending claims 15 and 27. In contrast, the *Nigella sativa* extract of the presently claimed invention comprises a purified polyunsaturated fatty acid fraction, e.g., saponified using 10% ethanolic KOH and subjected to the urea inclusion process several times so as to yield a fraction substantially devoid of contaminants (again, referring to Applicant's Figure 1, steps 4-7). Accordingly, Applicant respectfully submits that neither Ahmad nor Berg discloses the use of a semi-solid composition formulated for topical administration comprising a purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier. For this additional reason, Applicant submits that the Examiner's conclusion of obviousness is improper and should be withdrawn.

In sum, Applicant respectfully submits that the instant obviousness rejection is fundamentally flawed, lacking both legal and scientific foundation. As discussed above, in that the Examiner has failed to provide a motivation to combine the references as suggested, the combination can only be a result of impermissible hindsight vision afforded by the claimed invention. In addition, the suggested combination does not have a reasonable expectation of success, particularly considering the unpredictability and complexity of the art. Finally, the references as combined fail to yield the invention of the pending claims, including all the limitations thereof. Thus, Applicant respectfully submits that the rejection is improper and should be withdrawn.

As a final note, Applicant wishes to remind the Examiner that obvious features cannot serve as a basis for patentable distinction, and *vice versa*. In this case, a restriction/election of species requirement was issued on July 10, 2007. Therein, Applicant was required to elect one skin condition from among "psoriasis, eczema, dermatitis, dry, scaly, itchy or flaky skin, diaper rash, athlete's foot, jock itch, scalp irritations, and dermal infections". According to MPEP § 806.04, restriction among species within the scope of a generic claim may be proper if the species are independent or distinct. Species are deemed "independent" (i.e., "unrelated") only if they are not connected in any of design, operation, or effect under the disclosure. However, related inventions may be distinct if at least one invention is patentable (novel and nonobvious) over the other (though they may each be unpatentable over the prior art); otherwise, the disclosed relationship would preclude their being issued in separate patents. Accordingly, when making a requirement for restriction in an application claiming plural species, the examiner should group together species considered clearly unpatentable over each other. See MPEP § 806.04(h).

Similarly, when there is evidence that claimed inventions are obvious over each other within the meaning of 35 USC 103, restriction should not be required. See *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

Thus it would seem that a requirement for election of species must be premised on a finding of patentable distinction. Accordingly, Applicant submits that it is improper for the Examiner to subsequently characterize the selection of “diaper rash” from among the hundreds of known “skin diseases” (again see Appendix B: Wikipedia citation for “Skin Disease”) as merely “obvious” to one of ordinary skill in the art.

In sum, Applicant respectfully submits that the Examiner has failed to put forth a *prima facie* case of obviousness. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 9-11, 15, 18-21 and 26 under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.

*Ahmad in view of Berg & Nickavar:*

Claims 28-29 remain rejected under 35 U.S.C. § 103(a) as being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988) and Nickavar (Naturforsch, 2003). The Examiner submits that the Nickavar reference demonstrates that the quantity of *Nigella sativa* L extract utilized by Ahmad provides a composition that falls within the claimed range (i.e., a polyunsaturated fatty acid fraction no less than 16.5%).

Applicant respectfully disagrees and submits that the Nickavar reference fails to cure the above-noted deficiencies of Ahmad and Berg. In particular, Nickavar fails to provide a motivating suggestion to formulate a purified polyunsaturated fraction extracted from *Nigella sativa* L. seeds and a pharmaceutical carrier as a semi-solid composition suitable for topical administration and to utilize such in a method of treating skin conditions arising from fungal infection, bacterial infection, allergic reaction, or inflammation” as required by the claims as amended herewith.

Thus, in that the cited references, alone or in combination, fail to suggest the invention of the pending claims, Applicant respectfully submits that the conclusion of obviousness is in error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 28-29 under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.



Ahmad in view of Berg, Schlenk, and Ali:

Claim 27 remains rejected under 35 U.S.C. § 103(a) for being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988), Schlenk et al. (JACS, 1950), and Ali et al. (PTR, 2002).

Applicant respectfully disagrees and submits that the Schlenk and Ali references fail to cure the above-noted deficiencies of Ahmad and Berg. While Applicant does not dispute that the urea inclusion process utilized herein and described by Schlenk et al. was known in the art at the time of invention as a means to enrich an extract in polyunsaturated fatty acids, Applicant respectfully submits that none of the prior art references disclose the desirability of such selective enrichment. Accordingly, neither Schlenk nor Ali to provide a motivating suggestion to formulate a purified polyunsaturated fraction extracted from *Nigella sativa* L. seeds and a pharmaceutical carrier as a semi-solid composition suitable for topical administration and to utilize such in a method of treating skin conditions arising from fungal infection, bacterial infection, allergic reaction, or inflammation” as required by the claims as amended herewith.

Thus, in that the cited references, alone or in combination, fail to suggest the invention of the pending claims, Applicant respectfully submits that the conclusion of obviousness is in error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claim 27 under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.

**CONCLUSION**

The outstanding Office Action set a three-month shortened statutory period for response. Pursuant to the entry of Applicant’s petition for a one month extension of time, response is due on or before **August 1, 2008**. Accordingly, Applicant submits that this response is timely and that no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned’s Deposit Account No. **50-2101**.

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If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

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